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Notice of Allowability	Application No.	Applicant(s)	
	10/775,357	KONSTANTINO, EITAN	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment of 10/3/05.
2. ☒ The allowed claim(s) is/are 1-8, 12 and 13.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>12/27/05</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Heslin on 12/21/05 and 1/6/06.

The application has been amended as follows:

In claim 1 line 8 after "the catheter body" and before the period ".", --wherein the proximal end of the guidewire tube opens through a wall of the expandable region of the balloon—has been inserted.

Claims 9-11 have been cancelled.

In claim 12 line 1 after "any" and before "of claims", --one—has been inserted.

Allowable Subject Matter

Claims 1-8 and 12-13 are allowed.

The following is an examiner's statement of reasons for allowance:

The prior art fails to teach the combination of a balloon having an expandable region between proximal and distal ends where the proximal end is directly attached to a distal end of a catheter body and a guidewire tube having a lumen between proximal and distal ends where the proximal end of the tube is both spaced distally of the distal end of the catheter body and also opens through a wall of the expandable region of the balloon.

There are many prior art balloon catheters that are similar to the instant invention but none teach or render obvious the entirety of the combination above. Patents 6,248,092, 5,180,367, 6,485,457, 6,960,186 and 5,156,594 disclose balloon catheters with guidewire lumens at the distal end of the device. However, none of these devices teach, among all the limitations above, the proximal end of the guidewire opening through a wall of the expandable region of the balloon. One skilled in the art would not be motivated based on the references themselves, by a combination with another reference or by common knowledge in the art to modify the placement of the proximal end of the guidewire to open through the expandable region of the balloon since there is no teaching to make that modification. Additionally, patents 5,049,131 and 6,007,517 disclose balloon catheters with what appears to be lumens through the expandable regions of the balloons. However, these balloons do not disclose a tube that defines the lumen, the lumens do not go through the wall of the expandable region and these catheters do not teach the proximal end of the balloons being directly attached to the distal end of the catheter body. Instead, the distal end of the catheter body extends past the distal end of the balloon. One skilled in the art would not be motivated based on the references themselves, by a combination with another reference (including the ones listed above) or by common knowledge in the art to include a guidewire tube with a lumen, have the proximal end of the guidewire lumen open through a wall of the expandable region of the balloon and move the balloon so that the distal end of the catheter is attached directly to the proximal end of the balloon. Even if one were to combine all the elements of all the patents listed above, one still would not have a guidewire tube defining a guidewire lumen opening through a wall of the expandable region of a balloon where the

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proximal end of the balloon is directly attached to the distal end of a catheter body and the proximal end of the guidewire tube is distally spaced from the distal end of the catheter body.

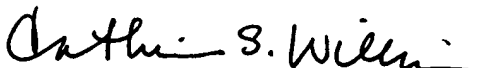
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Catherine S. Williams
January 9, 2006